



DEPARTMENT OF HEALTH & HUMAN SERVICES

HF-I-35

Public Health Service

M 1038 N

FOOD & DRUG ADMINISTRATION  
466 FERNANDEZ JUNCOS AVENUE  
SAN JUAN, P.R. 00901-3223

June 30, 1997

WARNING LETTER  
SJN-97-19

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. José María Pedrero  
President  
Pérez y Compañía de Puerto Rico, Inc.  
P. O. Box 10084  
San Juan, Puerto Rico 00908-0084

Dear Mr. Pedrero:

During an inspection of ship watering points at Piers 15 and 16 (Tender), San Juan, Puerto Rico, conducted on June 26 and 27, 1997, our inspector found deficiencies which are considered violations of the Public Health Service Act and the Interstate Conveyance Sanitation Regulations; Title 21, Code of Federal Regulations, 1240.83 (21 CFR 1240.83) and 1250.67 (21 CFR 1250.67).

Observations included, but were not limited to, the following deviations:

1. There are no backflow prevention devices on any of the twenty-five (25) water hydrants located at the Ship Repairs Area (10), the Shipping Division Area (9), East Side, or the Tender Pier Area (6), West side.
2. All but two hydrants were observed without a keeper's chain and cap protectors; the two hydrants with a cap on were observed with a brown, slimy material and rust inside the cap.
3. At least five water outlets were observed with brown-colored standing water, dirt and/or rust inside, and five were observed with a slimy, greenish/brown material on the outlet.
4. Garbage was observed accumulated next to various hydrants.
5. The water hose was observed improperly stored. The water hose was not in a locked and secured area, was observed inside a torn cardboard box stained with water and grease, and its ends were not protected from contamination. The water hose storage cabinet was observed filled with ropes and other waste materials.

Mr. Jose Maria Pedrero  
June 30, 1997

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The Inspectional Observations, as listed on a Form FDA-483, were discussed with Mr. Bertel Anderson, Yard Superintendent, on June 27, 1997. A copy of the FDA-483 is included for your review.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each applicable requirement of the Public Health Service Act and applicable regulations.

As a result of these observations, the watering points at Pier 15 are classified "NOT APPROVED" for servicing interstate carriers. A re-inspection to verify accomplishment of corrective actions will be scheduled as soon as you notify this office in writing of their completion.

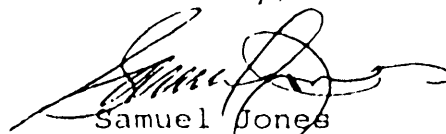
You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 466 Fernandez Juncos Avenue, Puerta de Tierra, San Juan, Puerto Rico 00901-3223.

If you require any assistance in understanding the contents of this letter, or if you desire a meeting with members of our staff, please contact Maridalia Torres, Acting Compliance Officer, at (787) 729-6894.

A copy of this letter is being forwarded to the agent for any interstate carrier identified as being serviced at these watering points.

Sincerely,

  
Samuel Jones  
District Director

Enclosure